INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

ISPM 11

PEST RISK ANALYSIS FOR QUARANTINE PESTS

(2013)

Produced by the Secretariat of the International Plant Protection Convention

Publication history

This is not an official part of the standard

1994-05 CEPM-1 added topic *PRA; Supplementary* (1994-003)

1995-02 EWG developed draft text

1995-05 CEPM-2 postponed the discussion

1996-05 CEPM-3 recommended for further study

1997-10 CEPM-4 discussed and requested further review

1998-05 CEPM-5 revised draft text and requested comments

1999-05 CEPM-6 discussed draft text and requested further discussion

1999-09 Supplementary CEPM revised draft text and approved for MC

1999 Sent for MC

2000-11 ISC-2 revised draft text for adoption

2001-04 ICPM-3 adopted standard

ISPM 11. 2001. *Pest risk analysis for quarantine pests*. Rome, IPPC, FAO.

1999-04 ICPM-2 added topic *GMO/Biodiversity/Invasive species* (1999-004)

1999-05 Open-ended PRA WG developed draft text

2000-06 EWG for definition the words Genetically modified organisms, LMOs and invasive species

2001-02 IPPC-CBD joint consultation

2001-04 ICPM-3 split topic *Risk analysis for environmental hazards of plant pests* (2001-001) and LMOs (1999-004)

2001-05 ISC approved Specification 5 *Risk analysis for environmental hazards of plants pests*

2002-05 SC revised draft text and approved for MC

2002-06 Sent for MC

2002-11 SC revised draft text for adoption

2003-04 ICPM-5 adopted Supplement 1(S1): *Analysis of environmental risks* (with Annex 1) to ISPM 11 and revised the title

ISPM 11. 2003. *Pest risk analysis for quarantine pests including analysis of environmental risks*. Rome, IPPC, FAO.

2001-09 Open-ended WG developed draft Specification 10 *Pest risk analysis for living modified organisms* (1999-004)

2002-03 ICPM-4 approved Specification 10: *Pest risk analysis for living modified organisms*

2002-09 EWG developed draft text

2003-05 SC-7 revised draft text and approved for MC

2003-06 Draft Sent for MC

2003-11 SC revised draft text with annexes

2004-04 ICPM-6 adopted Supplement 2 (S2): *Pest risk analysis for living modified organisms* (with Annexes 2, 3) to ISPM 11

2004-07 SC revised and approved integrated (S1+S2) standard

ISPM 11. 2004. *Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms*. Rome, IPPC, FAO.

2007-05 SC-7 approved Specification 44 rev. 1

2009-05 EWG drafted

2009-05 SC revised draft

2010-04 SC revised draft

2011-04 Steward revised ISPM based on comments

2011-05 SC approved for MC

2011-12 Steward revised ISPM based on comments

2012-03 Submitted to SC-7

2012-04 SC-7 revised and recommended to SC

2012-05 Submitted for 2012 SCCP

2012-11 SC revised and recommended for adoption by CPM

2013-04 CPM-8 adopted Annex 4 to ISPM 11 and consequential changes to core text

ISPM 11. 2013. *Pest risk analysis for quarantine pests.* Rome, IPPC, FAO.

Publication last updated: April 2013

CONTENTS

Adoption

ISPM 11 (*Pest risk analysis for quarantine pests*) was adopted by the Third Session of the Interim Commission on Phytosanitary Measures in April 2001. In April 2003, the Fifth Session of the Interim Commission on Phytosanitary Measures adopted a supplement to ISPM 11 on analysis of environmental risk and agreed that it should be integrated into ISPM 11. This resulted in ISPM 11 Rev. 1 (*Pest risk analysis for quarantine pests including analysis of environmental risks*). In April 2004, the Sixth Session of the Interim Commission on Phytosanitary Measures adopted a supplement on pest risk analysis for living modified organisms (LMOs) and agreed that it should be integrated into ISPM 11 Rev. 1. This has been done to produce the present standard, ISPM 11:2004. The supplementary text on environmental risks is marked with "S1" and the supplementary text on LMOs is marked with "S2".

The Interim Commission on Phytosanitary Measures acknowledges the collaboration and support of the Secretariat of the Convention on Biological Diversity, as well as the participation of experts from Parties to the Convention, in the preparation of the supplements to ISPM 11.

Annex 4 on pest risk analysis for plants as quarantine pests, together with associated changes in the core text of the standard, was adopted by the Eighth Session of the Commission on Phytosanitary Measures in April 2013.

INTRODUCTION

Scope

The standard provides details for the conduct of pest risk analysis (PRA) to determine if pests are quarantine pests. It describes the integrated processes to be used for risk assessment as well as the selection of risk management options.

S1 It also includes details regarding the analysis of risks of plant pests to the environment and biological diversity, including those risks affecting uncultivated/unmanaged plants, wild flora, habitats and ecosystems contained in the PRA area. Some explanatory comments on the scope of the IPPC in regard to environmental risks are given in Annex 1.

S2 It includes guidance on evaluating potential phytosanitary risks to plants and plant products posed by LMOs. This guidance does not alter the scope of ISPM 11 but is intended to clarify issues related to the PRA for LMOs. Some explanatory comments on the scope of the IPPC in regard to PRA for LMOs are given in Annex 2.

Specific guidance on conducting PRA for plants as quarantine pests is provided in Annex 4.

References

S2 **CBD.** 2000. *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*. Montreal, CBD.

ICPM. 2001. *Report of the Third Interim Commission on Phytosanitary Measures*, Rome, 2–6 April 2001. Rome, IPPC, FAO.

ICPM. 2005. *Report of the Seventh Interim Commission on Phytosanitary Measures*, Rome, 4–7 April 2005. Rome, IPPC, FAO.

IPPC. 1997. *International Plant Protection Convention*. Rome, IPPC, FAO.

ISPM 1. 1993. *Principles of plant quarantine as related to international trade*. Rome, IPPC, FAO. [published 1995] [revised; now ISPM 1:2006]

ISPM 2. 2007. *Framework for pest risk analysis*. Rome, IPPC, FAO.

ISPM 3. 1995. *Code of conduct for the import and release of exotic biological control agents***.** Rome, IPPC, FAO. [published 1996] [revised; now ISPM 3:2005]

ISPM 4. 1995. *Requirements for the establishment of pest free areas*. Rome, IPPC, FAO. [published 1996]

ISPM 5. *Glossary of phytosanitary terms*. Rome, IPPC, FAO.

ISPM 7. 1997. *Export certification system*. Rome, IPPC, FAO. [revised; now ISPM 7:2011]

ISPM 8. 1998. *Determination of pest status in an area*. Rome, IPPC, FAO.

ISPM 10. 1999. *Requirements for the establishment of pest free places of production and pest free production sites*. Rome, IPPC, FAO.

S2 **ISPM 12**. 2001. *Guidelines for phytosanitary certificates*. Rome, IPPC, FAO. [revised; now ISPM 12:2011]

ISPM 32. 2009. *Categorization of commodities according to their pest risk*. Rome, IPPC, FAO.

Definitions

Definitions of phytosanitary terms used in the present standard can be found in ISPM 5 (*Glossary of phytosanitary terms*).

Outline of Requirements

The objectives of a PRA are, for a specified area, to identify pests and/or pathways of quarantine concern and evaluate their risk, to identify endangered areas, and, if appropriate, to identify risk management options. PRA for quarantine pests follows a process defined by three stages:

- Stage 1 (initiating the process) involves identifying the pest(s) and pathways that are of quarantine concern and should be considered for risk analysis in relation to the identified PRA area.
- Stage 2 (risk assessment) begins with the categorization of individual pests to determine whether the criteria for a quarantine pest are satisfied. Risk assessment continues with an evaluation of the probability of pest entry, establishment, and spread, and of their potential economic consequences (including environmental consequences – S1).
- Stage 3 (risk management) involves identifying management options for reducing the risks identified at Stage 2. These are evaluated for efficacy, feasibility and impact in order to select those that are appropriate.

PEST RISK ANALYSIS FOR QUARANTINE PESTS

1. Stage 1: Initiation

The aim of the initiation stage is to identify the pest(s) and pathways which are of quarantine concern and should be considered for risk analysis in relation to the identified PRA area.

S2 Some LMOs may present a phytosanitary risk and therefore warrant a PRA. However other LMOs will not present phytosanitary risks beyond those posed by related non-LMOs and therefore will not warrant a complete PRA. Thus, for LMOs, the aim of the initiation stage is to identify those LMOs that have the characteristics of a potential pest and need to be assessed further, and those which need no further assessment under ISPM 11.

S2 LMOs are organisms that have been modified using techniques of modern biotechnology to express one or more new or altered traits. In most cases, the parent organism is not normally considered to be a plant pest but an assessment may need to be performed to determine if the genetic modification (i.e. gene, new gene sequence that regulates other genes, or gene product) results in a new trait or characteristic that may present a plant pest risk.

S2 A plant pest risk from LMOs may be presented by:

- the organism(s) with the inserted gene(s) (i.e. the LMO)
- the combination of genetic material (e.g. gene from plant pests such as viruses) or
- the consequences of the genetic material moving to another organism.

1.1 Initiation points

The PRA process may be initiated as a result of:

- the identification of a pathway that presents a potential pest hazard
- the identification of a pest that may require phytosanitary measures
- the review or revision of phytosanitary policies and priorities.

S1 The initiation points frequently refer to “pests”. The IPPC defines a pest as “any species, strain or biotype of plant, animal, or pathogenic agent, injurious to plants or plant products”. When applying these initiation points to the specific case of plants as pests, it is important to note that the plants concerned should satisfy this definition. Pests directly affecting plants satisfy this definition. In addition, many organisms indirectly affecting plants also satisfy this definition (such as plants as pests, e.g. weeds, invasive alien plants). The fact that they are injurious to plants may be based on evidence of their impact obtained in an area in which they occur. In the case where there is insufficient evidence that they affect plants indirectly, it may nevertheless be appropriate to assess – on the basis of available pertinent information – whether they are potentially injurious in the PRA area by using a clearly documented, consistently applied and transparent system. This is particularly important for plant species or cultivars that are imported for planting.

S2 The types of LMOs that a national plant protection organization (NPPO) may be asked to assess for phytosanitary risk include:

- plants for use (a) as agricultural crops, for food and feed, ornamental plants or managed forests; (b) in bioremediation (as an organism that cleans up contamination); (c) for industrial purposes (e.g. production of enzymes or bioplastics); (d) as therapeutic agents (e.g. pharmaceutical production)
- biological control agents modified to improve their performance in that role
- pests modified to alter their pathogenic characteristic and thereby make them useful for biological control (see ISPM 3:2005)

- organisms genetically modified to improve their characteristics such as for biofertilizer or other influences on soil, bioremediation or industrial uses.

S2 In order to be categorized as a pest, an LMO has to be injurious or potentially injurious to plants or plant products under conditions in the PRA area. This damage may be in the form of direct effects on plants or plant products, or indirect effects. For guidance on the process of determining whether an LMO has the potential to be a pest, refer to Annex 3, "Determining the potential for a living modified organism to be a pest".

1.1.1 PRA initiated by the identification of a pathway

The need for a new or revised PRA of a specific pathway may arise in the following situations:

- International trade is initiated in a commodity not previously imported into the country (usually a plant or plant product, including genetically altered plants) or a commodity from a new area or new country of origin.
- New plant species are imported for selection and scientific research purposes.
- A pathway other than commodity import is identified (natural spread, packing material, mail, garbage, passenger baggage etc.).

A list of pests likely to be associated with the pathway (e.g. carried by the commodity) may be generated by any combination of official sources, databases, scientific and other literature, or expert consultation. It is preferable to prioritize the listing, based on expert judgement on pest distribution and types of pests. If no potential quarantine pests are identified as likely to follow the pathway, the PRA may stop at this point.

S2 The phrase "genetically altered plants" is understood to mean plants obtained through the use of modern biotechnology.

1.1.2 PRA initiated by the identification of a pest

A requirement for a new or revised PRA on a specific pest may arise in the following situations:

- An emergency arises on discovery of an established infestation or an outbreak of a new pest within a PRA area.
- An emergency arises on interception of a new pest on an imported commodity.
- A new pest risk is identified by scientific research.
- A pest is introduced into an area.
- A pest is reported to be more damaging in an area other than in its area of origin.
- A pest is repeatedly intercepted.
- A request is made to import an organism.
- An organism is identified as a vector for other pests.
- An organism is genetically altered in a way which clearly identifies its potential as a plant pest.

S2 The phrase "genetically altered" is understood to include obtained through the use of modern biotechnology.

1.1.3 PRA initiated by the review or revision of a policy

A requirement for a new or revised PRA originating from policy concerns will most frequently arise in the following situations:

- A national decision is taken to review phytosanitary regulations, requirements or operations.
- A proposal made by another country or by an international organization (regional plant protection organization, FAO) is reviewed.
- A new treatment or loss of a treatment system, a new process, or new information impacts on an earlier decision.

- A dispute arises on phytosanitary measures.
- The phytosanitary situation in a country changes, a new country is created, or political boundaries have changed.

1.2 Identification of PRA area

The PRA area should be defined as precisely as possible in order to identify the area for which information is needed.

1.3 Information

Information gathering is an essential element of all stages of PRA. It is important at the initiation stage in order to clarify the identity of the pest(s), its/their present distribution and association with host plants, commodities etc. Other information will be gathered as required to reach necessary decisions as the PRA continues.

Information for PRA may come from a variety of sources. The provision of official information regarding pest status is an obligation under the IPPC (Article VIII.1(c)) facilitated by official contact points (Article VIII.2).

S1 For environmental risks, the variety of sources of information will generally be wider than traditionally used by NPPOs. Broader inputs may be required. These sources may include environmental impact assessments, but it should be recognized that such assessments usually do not have the same purpose as PRA and cannot substitute for PRA.

S2 For LMOs, information required for a full risk analysis may include:

- name, identity and taxonomic status of the LMO (including any relevant identifying codes) and the risk management measures applied to the LMO in the country of export
- taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism
- description of the nucleic acid or the modification introduced (including genetic construct) and the resulting genotypic and phenotypic characteristics of the LMO
- details of the transformation process
- appropriate detection and identification methods and their specificity, sensitivity and reliability
- intended use including intended containment
- quantity or volume of the LMO to be imported.

S2 Information regarding pest status is an obligation under the IPPC (Article VIII.1(c)) facilitated by official contact points (Article VIII.2). A country may have obligations to provide information about LMOs under other international agreements such as the *Cartagena Protocol on Biosafety to the Convention on Biological Diversity* (CBD, 2000). The Cartagena Protocol has a Biosafety Clearing-house that may contain relevant information. Information on LMOs is sometimes commercially sensitive and applicable obligations with regard to release and handling of information should be observed.

1.3.1 Previous PRA

A check should also be made as to whether pathways, pests or policies have already been subjected to the PRA process, either nationally or internationally. If a PRA exists, its validity should be checked as circumstances and information may have changed. The possibility of using a PRA from a similar pathway or pest, that may partly or entirely replace the need for a new PRA, should also be investigated.

1.4 Conclusion of initiation

At the end of Stage 1, the initiation point, the pests and pathways of concern and the PRA area will have been identified. Relevant information has been collected and pests have been identified as possible candidates for phytosanitary measures, either individually or in association with a pathway.

S2 For LMOs at the end of Stage 1 an NPPO may decide that the LMO:

- is a potential pest and needs to be assessed further in Stage 2 or
- is not a potential pest and needs no further analysis under ISPM 11 (but see also the following paragraph).

S2 PRA under the IPPC only relates to the assessment and management of phytosanitary risks. As with other organisms or pathways assessed by an NPPO, LMOs may present other risks not falling within the scope covered by the IPPC. For LMOs, PRA may constitute only a portion of the required overall risk analysis. For example, countries may require the assessment of risks to human or animal health or to the environment beyond that covered by the IPPC. When an NPPO discovers potential for risks that are not phytosanitary it may be appropriate to notify the relevant authorities.

2. Stage 2: Pest Risk Assessment

The process for pest risk assessment can be broadly divided into three interrelated steps:

- pest categorization
- assessment of the probability of introduction and spread
- assessment of potential economic consequences (including environmental impacts).

In most cases, these steps will be applied sequentially in a PRA but it is not essential to follow a particular sequence. Pest risk assessment needs to be only as complex as is technically justified by the circumstances. This standard allows a specific PRA to be judged against the principles of necessity, minimal impact, transparency, equivalence, risk analysis, managed risk and non-discrimination set out in ISPM 1:1993.

S2 For LMOs, from this point forward in PRA, it is assumed that the LMO is being assessed as a pest, and therefore “LMO” refers to an LMO that is a potential quarantine pest due to new or altered characteristics or properties resulting from the genetic modification. The risk assessment should be carried out on a case-by-case basis. LMOs that have pest characteristics unrelated to the genetic modification should be assessed using the normal procedures.

2.1 Pest categorization

At the outset, it may not be clear which pest(s) identified in Stage 1 require a PRA. The categorization process examines for each pest whether the criteria in the definition for a quarantine pest are satisfied.

In the evaluation of a pathway associated with a commodity, a number of individual PRAs may be necessary for the various pests potentially associated with the pathway. The opportunity to eliminate an organism or organisms from consideration before in-depth examination is undertaken is a valuable characteristic of the categorization process.

An advantage of pest categorization is that it can be done with relatively little information; however information should be sufficient to adequately carry out the categorization.

2.1.1 Elements of categorization

The categorization of a pest as a quarantine pest includes the following primary elements:

- identity of the pest
- presence or absence in the PRA area
- regulatory status

- potential for establishment and spread in PRA area
- potential for economic consequences (including environmental consequences) in the PRA area.

2.1.1.1 Identity of pest

The identity of the pest should be clearly defined to ensure that the assessment is being performed on a distinct organism, and that biological and other information used in the assessment is relevant to the organism in question. If this is not possible because the causal agent of particular symptoms has not yet been fully identified, then it should have been shown to produce consistent symptoms and to be transmissible.

The taxonomic unit for the pest is generally species. The use of a higher or lower taxonomic level should be supported by scientifically sound rationale. In the case of levels below the species, this should include evidence demonstrating that factors such as differences in virulence, host range or vector relationships are significant enough to affect phytosanitary status.

Specific guidance on the consideration of identity of plants as pests is provided in Annex 4.

In cases where a vector is involved, the vector may also be considered a pest to the extent that it is associated with the causal organism and is required for transmission of the pest.

S2 In the case of LMOs, identification requires information regarding characteristics of the recipient or parent organism, the donor organism, the genetic construct, the gene or transgene vector and the nature of the genetic modification. Information requirements are set out under section 1.3.

2.1.1.2 Presence or absence in PRA area

The pest should be absent from all or a defined part of the PRA area.

Specific guidance on determining the presence or absence of plants as pests is provided in Annex 4.

S2 In the case of LMOs, this should relate to the LMO of phytosanitary concern.

2.1.1.3 Regulatory status

If the pest is present but not widely distributed in the PRA area, it should be under official control or expected to be under official control in the near future.

S1 Official control of pests presenting an environmental risk may involve agencies other than the NPPO. However, it is recognized that ISPM 5 Supplement 1 (*Guidelines on the interpretation and application of the concept of official control for regulated pests*), in particular section 5.7, applies.

S2 In the case of LMOs, official control should relate to the phytosanitary measures applied because of the pest nature of the LMO. It may be appropriate to consider any official control measures in place for the parent organism, donor organism, transgene vector or gene vector.

2.1.1.4 Potential for establishment and spread in PRA area

Evidence should be available to support the conclusion that the pest could become established or spread in the PRA area. The PRA area should have ecological/climatic conditions including those in protected conditions suitable for the establishment and spread of the pest and where relevant, host species (or near relatives), alternate hosts and vectors should be present in the PRA area.

S2 For LMOs, the following should also be considered:

- changes in adaptive characteristics resulting from the genetic modification that may increase the potential for establishment and spread
- gene transfer or gene flow that may result in the establishment and spread of pests, or the emergence of new pests

- genotypic and phenotypic instability that could result in the establishment and spread of organisms with new pest characteristics, e.g. loss of sterility genes designed to prevent outcrossing.

S2 For more detailed guidance on the assessment of these characteristics, see Annex 3.

2.1.1.5 Potential for economic consequences in PRA area

There should be clear indications that the pest is likely to have an unacceptable economic impact (including environmental impact) in the PRA area.

S1 Unacceptable economic impact is described in ISPM 5 Supplement 2 (*Guidelines on the understanding of* potential economic importance *and related terms including reference to environmental considerations*).

S2 In the case of LMOs, the economic impact (including environmental impact) should relate to the pest nature (injurious to plants and plant products) of the LMO.

2.1.2 Conclusion of pest categorization

If it has been determined that the pest has the potential to be a quarantine pest, the PRA process should continue. If a pest does not fulfil all of the criteria for a quarantine pest, the PRA process for that pest may stop. In the absence of sufficient information, the uncertainties should be identified and the PRA process should continue.

2.2 Assessment of the probability of introduction and spread

Pest introduction is comprised of both entry and establishment. Assessing the probability of introduction requires an analysis of each of the pathways with which a pest may be associated from its origin to its establishment in the PRA area. In a PRA initiated by a specific pathway (usually an imported commodity), the probability of pest entry is evaluated for the pathway in question. The probabilities for pest entry associated with other pathways need to be investigated as well.

For risk analyses that have been initiated for a specific pest, with no particular commodity or pathway under consideration, the potential of all probable pathways should be considered.

The assessment of probability of spread is based primarily on biological considerations similar to those for entry and establishment.

S1 With respect to a plant being assessed as a pest with indirect effects, wherever a reference is made to a "host" or "host range", these terms should be understood to refer to a suitable habitat[1] in the PRA area.

S1 In the case of plants as pests, the concepts of entry, establishment and spread may have to be considered differently.

S1 For plants for planting proposed for import, the probability of entry need not be assessed. Following import, the plants may be planted and maintained in a particular location. The pest risk may arise if there is a possibility that the plants may spread from the location where they are intended to grow and establish in the endangered area. Accordingly, section 2.2.3 may be considered before section 2.2.2.

S1 Imported plants not intended to be planted may be used for various purposes (e.g. as bird seed, as fodder, or for processing). The pest risk of such plants may arise if there is a possibility that the plants may escape or be diverted from the intended use and establish in the endangered area.

Specific guidance on the consideration of habitats, locations and endangered area for plants as pests is provided in Annex 4.

[1] In the case of organisms that affect plants indirectly, through effects on other organisms, the terms host/habitat will extend also to those other organisms.

S2 Assessing the probability of introduction of an LMO requires an analysis of both intentional or unintentional pathways of introduction, and intended use.

2.2.1 Probability of entry of a pest

The probability of entry of a pest depends on the pathways from the exporting country to the destination, and the frequency and quantity of pests associated with them. The higher the number of pathways, the greater the probability of the pest entering the PRA area.

Documented pathways for the pest to enter new areas should be noted. Potential pathways, which may not currently exist, should be assessed. Pest interception data may provide evidence of the ability of a pest to be associated with a pathway and to survive in transport or storage.

S1 The probability of entry need not be assessed for plants that are proposed for import. However, the probability of entry needs to be assessed for pests that may be carried by such plants (e.g. contaminating seeds carried with seeds imported for planting).

Specific guidance on assessing the probability of entry for plants as pests is provided in Annex 4.

S2 This section is not relevant to LMOs imported for intentional release into the environment.

2.2.1.1 Identification of pathways for a PRA initiated by a pest

All relevant pathways should be considered. They can be identified principally in relation to the geographical distribution and host range of the pest. Consignments of plants and plant products moving in international trade are the principal pathways of concern and existing patterns of such trade will, to a substantial extent, determine which pathways are relevant. Other pathways such as other types of commodities, packing materials, persons, baggage, mail, conveyances and the exchange of scientific material should be considered where appropriate. Entry by natural means should also be assessed, as natural spread is likely to reduce the effectiveness of phytosanitary measures.

S2 For LMOs, all relevant pathways of introduction should be considered (intentional and unintentional).

2.2.1.2 Probability of the pest being associated with the pathway at origin

The probability of the pest being associated, spatially or temporally, with the pathway at origin should be estimated. Factors to consider are:

- prevalence of the pest in the source area
- occurrence of the pest in a life stage that would be associated with commodities, containers, or conveyances
- volume and frequency of movement along the pathway
- seasonal timing
- pest management, cultural and commercial procedures applied at the place of origin (application of plant protection products, handling, culling, roguing, grading).

2.2.1.3 Probability of survival during transport or storage

Examples of factors to consider are:

- speed and conditions of transport and duration of the life cycle of the pest in relation to time in transport and storage
- vulnerability of the life stages during transport or storage
- prevalence of pest likely to be associated with a consignment
- commercial procedures (e.g. refrigeration) applied to consignments in the country of origin, country of destination, or in transport or storage.

2.2.1.4 Probability of pest surviving existing pest management procedures

Existing pest management procedures (including phytosanitary procedures) applied to consignments against other pests from origin to end use, should be evaluated for effectiveness against the pest in question. The probability that the pest will go undetected during inspection or survive other existing phytosanitary procedures should be estimated.

2.2.1.5 Probability of transfer to a suitable host

Factors to consider are:

- dispersal mechanisms, including vectors to allow movement from the pathway to a suitable host
- whether the imported commodity is to be sent to a few or many destination points in the PRA area
- proximity of entry, transit and destination points to suitable hosts
- time of year at which import takes place
- intended use of the commodity (e.g. for planting, processing and consumption)
- risks from by-products and waste.

Some uses are associated with a much higher probability of introduction (e.g. planting) than others (e.g. processing). The probability associated with any growth, processing, or disposal of the commodity in the vicinity of suitable hosts should also be considered.

S2 For LMOs, the probability of gene flow and gene transfer should also be considered, when there is a trait of phytosanitary concern that may be transferred.

2.2.2 Probability of establishment

In order to estimate the probability of establishment of a pest, reliable biological information (life cycle, host range, epidemiology, survival etc.) should be obtained from the areas where the pest currently occurs. The situation in the PRA area can then be compared with that in the areas where it currently occurs (taking account also of protected environments such as glass- or greenhouses) and expert judgement used to assess the probability of establishment. Case histories concerning comparable pests can be considered. Examples of the factors to consider are:

- availability, quantity and distribution of hosts in the PRA area
- environmental suitability in the PRA area
- potential for adaptation of the pest
- reproductive strategy of the pest
- method of pest survival
- cultural practices and control measures.

In considering probability of establishment, it should be noted that a transient pest (see ISPM 8:1998) may not be able to establish in the PRA area (e.g. because of unsuitable climatic conditions) but could still have unacceptable economic consequences (see IPPC Article VII.3).

S1 In the case of plants as pests, assessment of the probability of establishment concerns their establishment in habitats other than those in which they are intended to grow.

Specific guidance on assessing the probability of establishment of plants as pests is provided in Annex 4.

S2 For LMOs, the survival capacity without human intervention should also be considered.

S2 In addition, where gene flow is a concern in the PRA area, the probability of expression and establishment of a trait of phytosanitary concern should be considered.

S2 Case histories concerning comparable LMOs or other organisms carrying the same construct can be considered.

2.2.2.1 Availability of suitable hosts, alternate hosts and vectors in the PRA area

Factors to consider are:

- whether hosts and alternate hosts are present and how abundant or widely distributed they may be
- whether hosts and alternate hosts occur within sufficient geographic proximity to allow the pest to complete its life cycle
- whether there are other plant species, which could prove to be suitable hosts in the absence of the usual host species
- whether a vector, if needed for dispersal of the pest, is already present in the PRA area or likely to be introduced
- whether another vector species occurs in the PRA area.

The taxonomic level at which hosts are considered should normally be the "species". The use of higher or lower taxonomic levels should be justified by scientifically sound rationale.

2.2.2.2 Suitability of environment

Factors in the environment (e.g. suitability of climate, soil, pest and host competition) that are critical to the development of the pest, its host and if applicable its vector, and to their ability to survive periods of climatic stress and complete their life cycles, should be identified. It should be noted that the environment is likely to have different effects on the pest, its host and its vector. This needs to be recognized in determining whether the interaction between these organisms in the area of origin is maintained in the PRA area to the benefit or detriment of the pest. The probability of establishment in a protected environment, e.g. in glasshouses, should also be considered.

Climatic modelling systems may be used to compare climatic data on the known distribution of a pest with that in the PRA area.

2.2.2.3 Cultural practices and control measures

Where applicable, practices employed during the cultivation/production of the host crops should be compared to determine if there are differences in such practices between the PRA area and the origin of the pest that may influence its ability to establish.

S2 For plants that are LMOs, it may also be appropriate to consider specific cultural, control or management practices.

Pest control programmes or natural enemies already in the PRA area which reduce the probability of establishment may be considered. Pests for which control is not feasible should be considered to present a greater risk than those for which treatment is easily accomplished. The availability (or lack) of suitable methods for eradication should also be considered.

2.2.2.4 Other characteristics of the pest affecting the probability of establishment

Other characteristics of the pest affecting the probability of establishment include:

- *Reproductive strategy of the pests and method of pest survival*. Characteristics, which enable the pest to reproduce effectively in the new environment, such as parthenogenesis/self-crossing, duration of the life cycle, number of generations per year, resting stage etc., should be identified.
- *Genetic adaptability*. Whether the species is polymorphic and the degree to which the pest has demonstrated the ability to adapt to conditions like those in the PRA area should be considered, e.g., host-specific races or races adapted to a wider range of habitats or to new hosts. This genotypic (and phenotypic) variability facilitates a pest's ability to withstand environmental

fluctuations, to adapt to a wider range of habitats, to develop pesticide resistance and to overcome host resistance.

- *Minimum population needed for establishment*. If possible, the threshold population that is required for establishment should be estimated.

S2 For LMOs, if there is evidence of genotypic and phenotypic instability, this should be considered.

S2 It may also be appropriate to consider proposed production and control practices related to the LMO in the country of import.

2.2.3 Probability of spread after establishment

A pest with a high potential for spread may also have a high potential for establishment, and possibilities for its successful containment and/or eradication are more limited. In order to estimate the probability of spread of the pest, reliable biological information should be obtained from areas where the pest currently occurs. The situation in the PRA area can then be carefully compared with that in the areas where the pest currently occurs and expert judgement used to assess the probability of spread. Case histories concerning comparable pests can usefully be considered. Examples of the factors to consider are:

- suitability of the natural and/or managed environment for natural spread of the pest
- presence of natural barriers
- the potential for movement with commodities or conveyances
- intended use of the commodity
- potential vectors of the pest in the PRA area
- potential natural enemies of the pest in the PRA area.

S1 In the case of plants as pests, assessment of spread concerns spread from the location where the plants are intended to grow or from the intended use to the endangered area.

Specific guidance on assessing the probability of spread of plants as pests is provided in Annex 4.

The information on probability of spread is used to estimate how rapidly a pest's potential economic importance may be expressed within the PRA area. This also has significance if the pest is liable to enter and establish in an area of low potential economic importance and then spread to an area of high potential economic importance. In addition it may be important in the risk management stage when considering the feasibility of containment or eradication of an introduced pest.

S1 Certain pests may not cause injurious effects on plants immediately after they establish, and in particular may only spread after a certain time. In assessing the probability of spread, this should be considered, based on evidence of such behaviour.

2.2.4 Conclusion on the probability of introduction and spread

The overall probability of introduction should be expressed in terms most suitable for the data, the methods used for analysis, and the intended audience. This may be quantitative or qualitative, since either output is in any case the result of a combination of both quantitative and qualitative information. The probability of introduction may be expressed as a comparison with that obtained from PRAs on other pests.

2.2.4.1 Conclusion regarding endangered areas

The part of the PRA area where ecological factors favour the establishment of the pest should be identified in order to define the endangered area. This may be the whole of the PRA area or a part of the area.

2.3 Assessment of potential economic consequences

Requirements described in this step indicate what information relative to the pest and its potential host plants should be assembled, and suggest levels of economic analysis that may be carried out using that information in order to assess all the effects of the pest, i.e. the potential economic consequences. Wherever appropriate, quantitative data that will provide monetary values should be obtained. Qualitative data may also be used. Consultation with an economist may be useful.

In many instances, detailed analysis of the estimated economic consequences is not necessary if there is sufficient evidence or it is widely agreed that the introduction of a pest will have unacceptable economic consequences (including environmental consequences). In such cases, risk assessment will primarily focus on the probability of introduction and spread. It will, however, be necessary to examine economic factors in greater detail when the level of economic consequences is in question, or when the level of economic consequences is needed to evaluate the strength of measures used for risk management or in assessing the cost-benefit of exclusion or control.

Specific guidance on assessing the potential economic consequences of plants as pests is provided in Annex 4.

S2 In the case of LMOs, the economic impact (including environmental impact) should relate to the pest nature (injurious to plants and plant products) of the LMO.

S2 For LMOs, the following evidence should also be considered:

- potential economic consequences that could result from adverse effects on non-target organisms that are injurious to plants or plant products
- economic consequences that could result from pest properties.

S2 For more detailed guidance on the assessment of these characteristics, see Annex 3.

2.3.1 Pest effects

In order to estimate the potential economic importance of the pest, information should be obtained from areas where the pest occurs naturally or has been introduced. This information should be compared with the situation in the PRA area. Case histories concerning comparable pests can usefully be considered. The effects considered may be direct or indirect.

S1 The basic method for estimating the potential economic importance of pests in this section also applies to:

- pests affecting uncultivated/unmanaged plants
- plants as pests
- pests affecting plants through effects on other organisms.

S1 In the case of direct and indirect environmental effects, specific evidence is needed.

S1 In the case of plants for planting that may be pests, the long-term consequences for the habitat in which the plants are intended to grow may be included in the assessment because planting may affect further use of or have a harmful effect on that habitat.

S1 Environmental effects and consequences considered should result from effects on plants. Such effects, however, on plants may be less significant than the effects and/or consequences on other organisms or systems. For example, a plant as a pest that has only a minor impact on plants may be significantly allergenic for humans or a minor plant pathogen may produce toxins that seriously affect livestock. However, the regulation of plants solely on the basis of their effects on other organisms or systems (e.g. on human or animal health) is outside the scope of this standard. If the PRA process reveals evidence of a potential hazard to other organisms or systems, this should be communicated to the appropriate authorities that have the legal responsibility to deal with the issue.

2.3.1.1 Direct pest effects

For identification and characterization of the direct effects of the pest on each potential host in the PRA area, or those effects which are host-specific, the following are examples that could be considered:

- known or potential host plants (in the field, under protected cultivation, or in the wild)
- types, amount and frequency of damage
- crop losses, in yield and quality
- biotic factors (e.g. adaptability and virulence of the pest) affecting damage and losses
- abiotic factors (e.g. climate) affecting damage and losses
- rate of spread
- rate of reproduction
- control measures (including existing measures), their efficacy and cost
- effect on existing production practices
- environmental effects.

For each of the potential hosts, the total area of the crop and area potentially endangered should be estimated in relation to the elements given above.

S1 In the case of the analysis of environmental risks, examples of direct pest effects on plants and/or their environmental consequences that could be considered include:

- reduction of keystone plant species
- reduction of plant species that are major components of ecosystems (in terms of abundance or size), and endangered native plant species (including effects below species level where there is evidence of such effects being significant)
- significant reduction, displacement or elimination of other plant species.

S1 The estimation of the area potentially endangered should relate to these effects.

2.3.1.2 Indirect pest effects

For identification and characterization of the indirect effects of the pest in the PRA area, or those effects that are not host-specific, the following are examples that could be considered:

- effects on domestic and export markets, including in particular effects on export market access (The potential consequences for market access which may result if the pest becomes established, should be estimated. This involves considering the extent of any phytosanitary regulations imposed (or likely to be imposed) by trading partners.)
- changes to producer costs or input demands, including control costs
- changes to domestic or foreign consumer demand for a product resulting from quality changes
- environmental and other undesired effects of control measures
- feasibility and cost of eradication or containment
- capacity to act as a vector for other pests
- resources needed for additional research and advice
- social and other effects (e.g. tourism).

S1 In the case of the analysis of environmental risks, examples of indirect pest effects on plants and/or their environmental consequences that could be considered include:

- significant effects on plant communities
- significant effects on designated environmentally sensitive or protected areas

- significant change in ecological processes and the structure, stability or processes of an ecosystem (including further effects on plant species, erosion, water table changes, increased fire hazard, nutrient cycling)
- effects on human use (e.g. water quality, recreational uses, tourism, animal grazing, hunting, fishing)
- costs of environmental restoration.

S1 Effects on human and animal health (e.g. toxicity, allergenicity), water tables, tourism etc. could also be considered, as appropriate, by other agencies/authorities.

2.3.2 Analysis of economic consequences

2.3.2.1 Time and place factors

Estimations made in the previous section related to a hypothetical situation where the pest is supposed to have been introduced and to be fully expressing its potential economic consequences (per year) in the PRA area. In practice, however, economic consequences are expressed with time, and may concern one year, several years or an indeterminate period. Various scenarios should be considered. The total economic consequences over more than one year can be expressed as net present value of annual economic consequences, and an appropriate discount rate selected to calculate net present value.

Other scenarios could concern whether the pest occurs at one, few or many points in the PRA area and the expression of potential economic consequences will depend on the rate and manner of spread in the PRA area. The rate of spread may be envisaged to be slow or rapid; in some cases, it may be supposed that spread can be prevented. Appropriate analysis may be used to estimate potential economic consequences over the period of time when a pest is spreading in the PRA area. In addition, many of the factors or effects considered above could be expected to change over time, with the consequent effects of potential economic consequences. Expert judgement and estimations will be required.

2.3.2.2 Analysis of commercial consequences

As determined above, most of the direct effects of a pest, and some of the indirect effects will be of a commercial nature, or have consequences for an identified market. These effects, which may be positive or negative, should be identified and quantified. The following may usefully be considered:

- effect of pest-induced changes to producer profits that result from changes in production costs, yields or prices
- effect of pest-induced changes in quantities demanded or prices paid for commodities by domestic and international consumers. This could include quality changes in products and/or quarantine-related trade restrictions resulting from a pest introduction.

2.3.2.3 Analytical techniques

There are analytical techniques which can be used in consultation with experts in economics to make a more detailed analysis of the potential economic effects of a quarantine pest. These should incorporate all of the effects that have been identified. These techniques may include:

- *Partial budgeting.* This will be adequate, if the economic effects induced by the action of the pest to producer profits are generally limited to producers and are considered to be relatively minor.
- *Partial equilibrium.* This is recommended if, under point 2.3.2.2, there is a significant change in producer profits, or if there is a significant change in consumer demand. Partial equilibrium analysis is necessary to measure welfare changes, or the net changes arising from the pest impacts on producers and consumers.
- *General equilibrium.* If the economic changes are significant to a national economy, and could cause changes to factors such as wages, interest rates or exchange rates, then general equilibrium analysis could be used to establish the full range of economic effects.

The use of analytical techniques is often limited by lack of data, by uncertainties in the data, and by the fact that for certain effects only qualitative information can be provided.

2.3.2.4 Non-commercial and environmental consequences

Some of the direct and indirect effects of the introduction of a pest determined in sections 2.3.1.1 and 2.3.1.2 will be of an economic nature, or affect some type of value, but not have an existing market which can be easily identified. As a result, the effects may not be adequately measured in terms of prices in established product or service markets. Examples include in particular environmental effects (such as ecosystem stability, biodiversity, amenity value) and social effects (such as employment, tourism) arising from a pest introduction. These impacts could be approximated with an appropriate non-market valuation method. More details on environment are given below.

If quantitative measurement of such consequences is not feasible, qualitative information about the consequences may be provided. An explanation of how this information has been incorporated into decisions should also be provided.

S1 Application of this standard to environmental hazards requires clear categorization of environmental values and how they can be assessed. The environment can be valued using different methodologies, but these methodologies are best used in consultation with experts in economics. Methodologies may include consideration of "use" and "non-use" values. "Use" values arise from consumption of an element of the environment, such as accessing clean water, or fishing in a lake, and also those that are non-consumptive, such as use of forests for leisure activities. "Non-use" values may be subdivided into:

- "option value" (value for use at a later date)
- "existence value" (knowledge that an element of the environment exists)
- "bequest value" (knowledge that an element of the environment is available for future generations).

S1 Whether the element of the environment is being assessed in terms of use or non-use values, methods exist for their valuation, such as market-based approaches, surrogate markets, simulated markets, and benefit transfer. Each has advantages, disadvantages and situations where it is particularly useful.

S1 The assessment of consequences may be either quantitative or qualitative and in many cases, qualitative data is sufficient. A quantitative method may not exist to address a situation (e.g. catastrophic effects on a keystone species), or a quantitative analysis may not be possible (no methods available). Useful analyses can be based on non-monetary valuations (number of species affected, water quality), or expert judgement, if the analyses follow documented, consistent and transparent procedures.

S1 Economic impact is described in ISPM 5 Supplement 2 (*Guidelines on the understanding of* potential economic importance *and related terms including reference to environmental considerations*).

2.3.3 Conclusion of the assessment of economic consequences

Wherever appropriate, the output of the assessment of economic consequences described in this step should be in terms of a monetary value. The economic consequences can also be expressed qualitatively or using quantitative measures without monetary terms. Sources of information, assumptions and methods of analysis should be clearly specified.

2.3.3.1 Endangered area

The part of the PRA area where presence of the pest will result in economically important loss should be identified as appropriate. This is needed to define the endangered area.

2.4 Degree of uncertainty

Estimation of the probability of introduction of a pest and of its economic consequences involves many uncertainties. In particular, this estimation is an extrapolation from the situation where the pest occurs to the hypothetical situation in the PRA area. It is important to document the areas of uncertainty and the degree of uncertainty in the assessment, and to indicate where expert judgement has been used. This is necessary for transparency and may also be useful for identifying and prioritizing research needs.

S1 It should be noted that the assessment of the probability and consequences of environmental hazards of pests of uncultivated and unmanaged plants often involves greater uncertainty than for pests of cultivated or managed plants. This is due to the lack of information, additional complexity associated with ecosystems, and variability associated with pests, hosts or habitats.

2.5 Conclusion of the pest risk assessment stage

As a result of the pest risk assessment, all or some of the categorized pests may be considered appropriate for pest risk management. For each pest, all or part of the PRA area may be identified as an endangered area. A quantitative or qualitative estimate of the probability of introduction of a pest or pests, and a corresponding quantitative or qualitative estimate of economic consequences (including environmental consequences), have been obtained and documented or an overall rating could have been assigned. These estimates, with associated uncertainties, are utilized in the pest risk management stage of the PRA.

3. Stage 3: Pest Risk Management

The conclusions from pest risk assessment are used to decide whether risk management is required and the strength of measures to be used. Since zero-risk is not a reasonable option, the guiding principle for risk management should be to manage risk to achieve the required degree of safety that can be justified and is feasible within the limits of available options and resources. Pest risk management (in the analytical sense) is the process of identifying ways to react to a perceived risk, evaluating the efficacy of these actions, and identifying the most appropriate options. The uncertainty noted in the assessments of economic consequences and probability of introduction should also be considered and included in the selection of a pest management option.

S1 In considering the management of environmental risks, it should be stressed that phytosanitary measures are intended to account for uncertainty and should be designed in proportion to the risk. Pest risk management options should be identified, taking account of the degree of uncertainty in the assessment of economic consequences, probability of introduction, and the respective technical justification of those options. In this respect, the management of risks to the environment caused by plant pests does not differ from the management of other plant pest risks.

Specific guidance on pest risk management for plants as pests is provided in Annex 4.

3.1 Level of risk

The principle of "managed risk" (ISPM 1:1993, *Principles of plant quarantine as related to international trade*) states that: "Because some risk of introduction of a quarantine pest always exists, countries shall agree to a policy of risk management when formulating phytosanitary measures." In implementing this principle, countries should decide what level of risk is acceptable to them.

The acceptable level of risk may be expressed in a number of ways, such as:

- reference to existing phytosanitary requirements
- indexed to estimated economic losses
- expressed on a scale of risk tolerance
- compared with the level of risk accepted by other countries.

S2 For LMOs, the acceptable level of risk may also be expressed by comparison to the level of risk associated with similar or related organisms, based on their characteristics and behaviour in a similar environment to the PRA area.

3.2 Technical information required

The decisions to be made in the pest risk management process will be based on the information collected during the preceding stages of PRA. This information will be composed of:

- reasons for initiating the process
- estimation of the probability of introduction to the PRA area
- evaluation of potential economic consequences in the PRA area.

3.3 Acceptability of risk

Overall risk is determined by the examination of the outputs of the assessments of the probability of introduction and the economic impact. If the risk is found to be unacceptable, then the first step in risk management is to identify possible phytosanitary measures that will reduce the risk to, or below an acceptable level. Measures are not justified if the risk is already acceptable or must be accepted because it is not manageable (as may be the case with natural spread). Countries may decide that a low level of monitoring or audit is maintained to ensure that future changes in the pest risk are identified.

3.4 Identification and selection of appropriate risk management options

Appropriate measures should be chosen based on their effectiveness in reducing the probability of introduction of the pest. The choice should be based on the following considerations, which include several of the phytosanitary principles of ISPM 1:1993:

- *Phytosanitary measures shown to be cost-effective and feasible*. The benefit from the use of phytosanitary measures is that the pest will not be introduced and the PRA area will, consequently, not be subjected to the potential economic consequences. The cost-benefit analysis for each of the minimum measures found to provide acceptable security may be estimated. Those measures with an acceptable benefit-to-cost ratio should be considered.
- *Principle of "minimal impact"*. Measures should not be more trade restrictive than necessary. Measures should be applied to the minimum area necessary for the effective protection of the endangered area.
- *Reassessment of previous requirements*. No additional measures should be imposed if existing measures are effective.
- *Principle of "equivalence"*. If different phytosanitary measures with the same effect are identified, they should be accepted as alternatives.
- *Principle of "non-discrimination"*. If the pest under consideration is established in the PRA area but of limited distribution and under official control, the phytosanitary measures in relation to import should not be more stringent than those applied within the PRA area. Likewise, phytosanitary measures should not discriminate between exporting countries of the same phytosanitary status.

S1 The principle of non-discrimination and the concept of official control also apply to:

- pests affecting uncultivated/unmanaged plants
- plants as pests
- pests affecting plants through effects on other organisms.

S1 If any of these become established in the PRA area and if official control is applied, then phytosanitary measures at import should not be more stringent than the official control measures.

The major risk of introduction of plant pests is with imported consignments of plants and plant products, but (especially for a PRA performed on a particular pest) it is necessary to consider the risk

of introduction with other types of pathways (e.g. packing materials, conveyances, travellers and their luggage, and the natural spread of a pest).

The measures listed below are examples of those that are most commonly applied to traded commodities. They are applied to pathways, usually consignments of a host, from a specific origin. The measures should be as precise as possible as to consignment type (hosts, parts of plants) and origin so as not to act as barriers to trade by limiting the import of products where this is not justified. Combinations of two or more measures may be needed in order to reduce the risk to an acceptable level. The available measures can be classified into broad categories which relate to the pest status of the pathway in the country of origin. These include measures:

- applied to the consignment
- applied to prevent or reduce original infestation in the crop
- to ensure the area or place of production is free from the pest
- concerning the prohibition of commodities.

Other options may arise in the PRA area (restrictions on the use of a commodity), control measures, introduction of a biological control agent, eradication and containment. Such options should also be evaluated and will apply in particular if the pest is already present but not widely distributed in the PRA area.

3.4.1 Options for consignments

Measures may include any combinations of the following:

- inspection or testing for freedom from a pest or to a specified pest tolerance – sample size should be adequate to give an acceptable probability of detecting the pest
- prohibition of parts of the host
- a pre-entry or post-entry quarantine system – this system could be considered to be the most intensive form of inspection or testing where suitable facilities and resources are available, and may be the only option for certain pests not detectable on entry
- specified conditions of preparation of the consignment (e.g. handling to prevent infestation or reinfestation)
- specified treatment of the consignment – such treatments are applied post-harvest and could include chemical, thermal, irradiation or other physical methods
- restrictions on end use, distribution and periods of entry of the commodity.

Measures may also be applied to restrict the import of consignments of pests.

S1 The concept of consignments of pests may be applied to the import of plants considered to be pests. These consignments may be restricted to species or varieties posing less risk.

S2 For LMOs, as for other organisms, information may have been obtained concerning the risk management measures applied to the LMO in the country of export (see section 1.3). These should be assessed to determine if they are appropriate for the conditions in the PRA area and, if appropriate, the intended use.

S2 For LMOs, measures may also include procedures for the provision of information on the phytosanitary integrity of consignments (e.g. tracing systems, documentation systems, identity preservation systems).

3.4.2 Options preventing or reducing infestation in the crop

Measures may include:

- treatment of the crop, field, or place of production
- restriction of the composition of a consignment so that it is composed of plants belonging to resistant or less susceptible species

- growing plants under specially protected conditions (glasshouse, isolation)
- harvesting of plants at a certain age or a specified time of year
- production in a certification scheme. An officially monitored plant production scheme usually involves a number of carefully controlled generations, beginning with nuclear stock plants of high health status. It may be specified that the plants be derived from plants within a limited number of generations.

S2 Measures may be applied to reduce the probability that LMOs (or genetic material from LMOs) that pose a phytosanitary risk could be in other crops. These include:

- management systems (e.g. buffer zones, refugia)
- management of trait expression
- control of reproductive ability (e.g. male sterility)
- control of alternative hosts.

3.4.3 Options ensuring that the area, place or site of production or crop is free from the pest

Measures may include:

- pest-free area – requirements for pest-free area status are described in ISPM 4:1995
- pest-free place of production or pest-free production site – requirements are described in ISPM 10:1999
- inspection of crop to confirm pest freedom.

3.4.4 Options for other types of pathways

For many types of pathways, the measures considered above for plants and plant products to detect the pest in the consignment or to prevent infestation of the consignment, may also be used or adapted. For certain types of pathways, the following factors should be considered:

- Natural spread of a pest includes movement of the pest by flight, wind dispersal, transport by vectors such as insects or birds and natural migration. If the pest is entering the PRA area by natural spread, or is likely to enter in the immediate future, phytosanitary measures may have little effect. Control measures applied in the area of origin could be considered. Similarly, containment or eradication, supported by suppression and surveillance, in the PRA area after entry of the pest could be considered.
- Measures for human travellers and their baggage could include targeted inspections, publicity and fines or incentives. In a few cases, treatments may be possible.
- Contaminated machinery or modes of transport (ships, trains, planes, road transport) could be subjected to cleaning or disinfestation.

3.4.5 Options within the importing country

Certain measures applied within the importing country may also be used. These could include careful surveillance to try and detect the entry of the pest as early as possible, eradication programmes to eliminate any foci of infestation and/or containment action to limit spread.

S1 For plants to be imported, where there is a high level of uncertainty regarding pest risk, it may be decided not to take phytosanitary measures at import, but only to apply surveillance or other procedures after entry (e.g. by or under the supervision of the NPPO).

S2 The potential for risk from LMO pests depends in part on the intended use. As for other organisms, certain intended uses (such as high security contained use) may significantly manage risk.

S2 For LMOs, as with other pests, options within the country also include the use of emergency measures related to phytosanitary risks. Any emergency measures should be consistent with Article VII.6 of the IPPC.

3.4.6 Prohibition of commodities

If no satisfactory measure to reduce risk to an acceptable level can be found, the final option may be to prohibit importation of the relevant commodities. This should be viewed as a measure of last resort and should be considered in light of the anticipated efficacy, especially in instances where the incentives for illegal import may be significant.

3.5 Phytosanitary certificates and other compliance measures

Risk management includes the consideration of appropriate compliance procedures. The most important of these is export certification (see ISPM 7:1997). The issuance of phytosanitary certificates (see ISPM 12:2001) provides official assurance that a consignment is "considered to be free from the quarantine pests specified by the importing contracting party and to conform with the current phytosanitary requirements of the importing contracting party." It thus confirms that the specified risk management options have been followed. An additional declaration may be required to indicate that a particular measure has been carried out. Other compliance measures may be used subject to bilateral or multilateral agreement.

S2 Information on phytosanitary certificates regarding LMOs (as with any other regulated articles) should only be related to phytosanitary measures (see ISPM 12:2001).

3.6 Conclusion of pest risk management

The result of the pest risk management procedure will be either that no measures are identified which are considered appropriate or the selection of one or more management options that have been found to lower the risk associated with the pest(s) to an acceptable level. These management options form the basis of phytosanitary regulations or requirements.

The application and maintenance of such regulations is subject to certain obligations in the case of contracting parties to the IPPC.

S1 Phytosanitary measures taken in relation to environmental hazards should, as appropriate, be notified to relevant competent authorities responsible for national biodiversity policies, strategies and action plans.

S1 It is noted that the communication of risks associated with environmental hazards is of particular importance to promote awareness.

Specific guidance on risk communication for plants as pests is provided in Annex 4.

3.6.1 Monitoring and review of phytosanitary measures

The principle of "modification" states: "As conditions change, and as new facts become available, phytosanitary measures shall be modified promptly, either by inclusion of prohibitions, restrictions or requirements necessary for their success, or by removal of those found to be unnecessary" (ISPM 1:1993, *Principles of plant quarantine as related to international trade*).

Thus, the implementation of particular phytosanitary measures should not be considered to be permanent. After application, the success of the measures in achieving their aim should be determined by monitoring during use. This is often achieved by inspection of the commodity on arrival, noting any interceptions or any entries of the pest to the PRA area. The information supporting the pest risk analysis should be periodically reviewed to ensure that any new information that becomes available does not invalidate the decision taken.

4. Documentation of Pest Risk Analysis

4.1 Documentation requirements

The IPPC and the principle of "transparency" (ISPM 1:1993) require that countries should, on request, make available the rationale for phytosanitary requirements. The whole process from initiation to pest

risk management should be sufficiently documented so that when a review or a dispute arises, the sources of information and rationale used in reaching the management decision can be clearly demonstrated.

The main elements of documentation are:

- purpose for the PRA
- pest, pest list, pathways, PRA area, endangered area
- sources of information
- categorized pest list
- conclusions of risk assessment
  - . probability
  - . consequences
- risk management
  - . options identified
  - . options selected.

This annex was adopted as part of a supplement by the Fifth Session of the Interim Commission on Phytosanitary Measures in April 2003.

The annex is a prescriptive part of the standard.

S1 ANNEX 1: Comments on the scope of the IPPC in regard to environmental risks

The range of pests covered by the IPPC extends beyond pests directly affecting cultivated plants. The coverage of the IPPC definition of pests includes plants as pests and other species that have indirect effects on plants, and the Convention applies to the protection of wild flora. The scope of the IPPC also extends to organisms that are pests because they:

- *directly affect uncultivated/unmanaged plants*

Introduction of these pests may have few commercial consequences, and therefore they have been less likely to be evaluated, regulated and/or placed under official control. An example of this type of pest is Dutch elm disease (*Ophiostoma novo-ulmi*).

- *indirectly affect plants*

In addition to pests that directly affect host plants, there are those, like most plants as pests (e.g. weeds and invasive plants), that affect plants primarily by other processes such as competition.

- *indirectly affect plants through effects on other organisms*

Some pests may primarily affect other organisms, but thereby cause deleterious effects on plant species, or plant health in habitats or ecosystems. Examples include parasites of beneficial organisms, such as biological control agents.

To protect the environment and biological diversity without creating disguised barriers to trade, environmental risks and risks to biological diversity should be analysed in a PRA.

This annex was adopted by the Sixth Session of the Interim Commission on Phytosanitary Measures in March–April 2004.
The annex is a prescriptive part of the standard.

S2 ANNEX 2: Comments on the scope of the IPPC in regard to pest risk analysis for living modified organisms

Phytosanitary risks that may be associated with a living modified organism are within the scope of the International Plant Protection Convention and should be considered using pest risk analysis to make decisions regarding pest risk management.

The analysis of LMOs includes consideration of the following:

- Some LMOs may present a phytosanitary risk and therefore warrant a PRA. However other LMOs will not present a phytosanitary risks beyond those posed by related non-LMOs and therefore will not warrant a complete PRA. For example, modifications to change the physiological characteristics of a plant (e.g. ripening time, storage life) may not present any phytosanitary risk. The pest risk that may be posed by an LMO is dependent on a combination of factors, including the characteristics of the donor and recipient organisms, the genetic alteration, and the specific new trait or traits. Therefore, part of the supplementary text (see Annex 3) provides guidance on how to determine if an LMO is a potential pest.
- PRA may constitute only a portion of the overall risk analysis for import and release of a LMO. For example, countries may require the assessment of risks to human or animal health, or to the environment, beyond that covered by the IPPC. This standard only relates to the assessment and management of phytosanitary risks. As with other organisms or pathways assessed by an NPPO, LMOs may present other risks not falling within the scope of the IPPC. When an NPPO discovers potential for risks that are not of phytosanitary concern it may be appropriate to notify the relevant authorities.
- Phytosanitary risks from LMOs may result from certain traits introduced into the organism, such as those that increase the potential for establishment and spread, or from inserted gene sequences that do not alter the pest characteristics of the organism but that might act independently of the organism or have unintended consequences.
- In cases of phytosanitary risks related to gene flow, the LMO is acting more as a potential vector or pathway for introduction of a genetic construct of phytosanitary concern rather than as a pest in and of itself. Therefore, the term “pest” should be understood to include the potential of an LMO to act as a vector or pathway for introduction of a gene presenting a potential phytosanitary risk.
- The risk analysis procedures of the IPPC are generally concerned with phenotypic characteristics rather than genotypic characteristics. However, genotypic characteristics may need to be considered when assessing the phytosanitary risks of LMOs.
- Potential phytosanitary risks that may be associated with LMOs could also be associated with non-LMOs. It may be useful to consider risks associated with LMOs in the context of risks posed by the non-modified recipient or parental organisms, or similar organisms, in the PRA area.

This annex was adopted by the Sixth Session of the Interim Commission on Phytosanitary Measures in March–April 2004.
The annex is a prescriptive part of the standard.

S2 ANNEX 3: Determining the potential for a living modified organism to be a pest

This annex is relevant for living modified organisms only where there is potential for phytosanitary risks from the LMO associated with some characteristic or property related to the genetic modification. Other phytosanitary risks associated with the organism should be assessed under other appropriate sections of ISPM 11 or under other appropriate ISPMs.

The information requirements outlined in section 1.3 may be needed in determining the potential for an LMO to be a pest.

Potential phytosanitary risks for LMOs

Potential phytosanitary risks for LMOs may include:

a. Changes in adaptive characteristics which may increase the potential for introduction or spread, for example alterations in:

- tolerance to adverse environmental conditions (e.g. drought, freezing, salinity)
- reproductive biology
- dispersal ability of pests
- growth rate or vigour
- host range
- pest resistance
- pesticide (including herbicide) resistance or tolerance.

b. Adverse effects of gene flow or gene transfer including, for example:

- transfer of pesticide or pest resistance genes to compatible species
- the potential to overcome existing reproductive and recombination barriers resulting in pest risks
- potential for hybridization with existing organisms or pathogens to result in pathogenicity or increased pathogenicity.

c. Adverse effects on non-target organisms including, for example:

- changes in host range of the LMO, including the cases where it is intended for use as a biological control agent or organism otherwise claimed to be beneficial
- effects on other organisms, such as biological control agents, beneficial organisms, or soil fauna and microflora, nitrogen-fixing bacteria, that result in a phytosanitary impact (indirect effects)
- capacity to vector other pests
- negative direct or indirect effects of plant-produced pesticides on non-target organisms beneficial to plants.

d. Genotypic and phenotypic instability including, for example:

- reversion of an organism intended as a biocontrol agent to a virulent form.

e. Other injurious effects including, for example:

- phytosanitary risks presented by new traits in organisms that do not normally pose phytosanitary risk
- novel or enhanced capacity for virus recombination, trans-encapsidation and synergy events related to the presence of virus sequences
- phytosanitary risks resulting from nucleic acid sequences (markers, promoters, terminators etc.) present in the insert.

The potential phytosanitary risks identified above can also be associated with non-LMOs. The risk analysis procedures of the IPPC are generally concerned with phenotypic characteristics rather than genotypic characteristics. However, genotypic characteristics may need to be considered when assessing the phytosanitary risks of LMOs.

If there is no indication that new traits resulting from genetic modifications have phytosanitary risks, the LMO may require no further consideration.

It may be useful to consider potential risks in the context of risks posed by the non-modified recipients or parental organisms, or similar organisms, in the PRA area.

In cases of phytosanitary risks related to gene flow, the LMO is acting more as a potential vector or pathway for introduction of a genetic construct of phytosanitary concern rather than as a pest in and of itself. Therefore, the term "pest" should be understood to include the potential of an LMO to act as a vector or pathway for introduction of a gene presenting a potential phytosanitary risk.

Factors that may result in the need to subject a LMO to Stage 2 of the PRA include:

- lack of knowledge about a particular modification event
- the credibility of information if it is an unfamiliar modification event
- insufficient data on the behaviour of the LMO in environments similar to the PRA area
- field experience, research trials or laboratory data indicating that the LMO may pose phytosanitary risks (see subsections a. to e. above)
- where the LMO expresses characteristics that are associated with pests under ISPM 11
- existing conditions in the country (or PRA area) that may result in the LMO being a pest
- where there are PRAs for similar organisms (including LMOs) or risk analyses carried out for other purposes that indicate a pest potential
- experience in other countries.

Factors that may lead to the conclusion that an LMO is not a potential pest and/or requires no further consideration under ISPM 11 include:

- where the genetic modification in similar or related organisms has previously been assessed by the NPPO (or other recognized experts or agencies) as having no phytosanitary risk
- where the LMO is to be confined in a reliable containment system and not be released
- evidence from research trials that the LMO is unlikely to be a pest under the use proposed
- experience in other countries.

This annex was adopted by the Eighth Session of the Commission on Phytosanitary Measures in April 2013.

The annex is a prescriptive part of the standard.

ANNEX 4: Pest risk analysis for plants as quarantine pests

Introduction

This annex provides specific guidance on conducting PRA to determine if a plant is a pest of cultivated or wild plants, whether it should be regulated, and to identify phytosanitary measures that reduce the pest risk to an acceptable level. It focuses primarily on plants proposed for import, whether as plants for planting or for other intended uses. It does not cover the unintentional introduction of plants as contaminants in commodities or conveyances.

The number and diversity of plants being moved between and within countries is increasing as opportunities for trade increase and markets develop for new plants. Movements of plants may imply two types of pest risk: the plant (as a pathway) may carry pests, or the plant itself may be a pest. The risk of introducing pests with plants as a pathway has long been recognized and widely regulated. However, pest risk posed by plants as pests requires specific consideration.

Plants as pests

Plants as pests may affect other plants through competition for space and resources, such as light, nutrients and water, or through parasitism or allelopathy. Plants introduced to a new area may also become pests by hybridizing with cultivated plants or wild plants.

Thus, the protection of plants as pursued through the IPPC may include considering certain plants as pests, and taking phytosanitary measures to prevent their introduction and spread. Determining which plants are pests is context-specific and may vary with geography, habitat, land use, time and the perceived value of the natural resources in the endangered area. PRA should form the basis of such a determination and subsequent decisions regarding possible regulation of the plant species as a quarantine pest. It should be noted that plants having undergone such analysis may also require assessment of their potential to be pathways for other pests.

The IPPC has recognized the importance of plants as pests by underscoring that the definition of "pest" includes weeds (ICPM, 2001), and by specifically including "plants that are invasive alien species" in a range of recommendations for action for those invasive alien species that are pests of plants (ICPM, 2005). This annex provides some specific guidance on how to apply these recommendations. The 2004 revision of ISPM 11 introduced specific elements of conducting a PRA for plants as pests that are further elaborated in this annex.

The IPPC is concerned with pests injurious to cultivated and wild plants (see Annex 1 of this standard), and therefore weeds and invasive plants that are injurious to other plants should be considered pests in the IPPC context. Henceforth in this annex, the terms "weed" and "invasive plants" are not used, but only the single term "plants as pests"[2].

The remainder of the text generally follows the sequence of ISPM 11:2004, with the corresponding sections of the standard indicated in parentheses. In each section, guidance is provided on the analytical aspects particular to plants as pests.

[2] "Invasive plants" are often taken to mean invasive alien species in the CBD sense (see ISPM 5, Appendix 1 (2009)). The term "weed" usually refers to pests of cultivated plants. However, some countries use the term "weed" irrespective of whether cultivated plants or wild flora are at risk, and other countries use the term "noxious weed", "landscape weed", "environmental weed" or similar terms to distinguish them from plants only affecting crops.

Stage 1: Initiation

Initiation points

The PRA process for plants as quarantine pests will most frequently arise in situations such as:

- a request is made to import a plant not previously imported
- a plant already available and used in a country is suspected of posing a pest risk, e.g. because of new evidence or anticipated changes in its intended use
- a decision is made to review or revise phytosanitary policies.

Pre-selection

ISPM 2:2007 describes, as part of the initiation stage, a pre-selection step intended for determining whether or not an organism is a pest, and provides some indicators that a plant may be a pest. Particular attention is needed for plants that have proven to be pests elsewhere or that have intrinsic characteristics such as high propagation rate or strong competitive or propagule dispersal abilities. In most cases, consideration of these factors in Stage 1 of the PRA may not be sufficient to terminate the process; however, in cases where it is clearly determined that the plant is only suited to a specific type of habitat that does not exist in the PRA area, it may be concluded that the plant cannot become a pest in that area and the PRA process may stop at that point.

Stage 2: Pest risk assessment

Identity of the plant (refer to section 2.1.1.1)

The species is the taxonomic level usually considered in PRA. However, in the case of cultivated plants that may be pests, lower taxonomic levels may be used where there are scientifically sound rationales. The taxonomic level appropriate for conducting the PRA for a particular plant as a pest should be determined by the NPPO.

Some particular considerations regarding the identity of plants as pests may include the following:

- The taxonomic identity of the plant may be unclear because it has been obscured by breeding or hybridization or is the subject of plant breeders' rights. This is particularly relevant for horticultural plants. The NPPO should acquire the best possible information about the identity and parentage of the plant from various sources (e.g. the prospective importer, plant breeders, scientific literature).
- The use of taxonomic levels below the species (i.e. subspecies, variety, cultivar) may be justified if there is scientific evidence demonstrating that differences in characteristics are stable and significantly affect phytosanitary status. Examples may include differences in adaptability to environmental conditions, ability to exploit resources, ability to defend against herbivores, and methods of reproduction or propagule dispersal.
- The evaluation of a hybrid should be based on information specific to that hybrid where available. Where such information does not exist, PRA may be conducted on the parent species to determine their pest risk. If either parent is determined to be a pest and the associated risk is deemed unacceptable, this information may form the basis of the risk assessment for the hybrid. However, as hybrids do not always express similar characteristics to their parent species, that approach may significantly increase the assessment uncertainty and should be used with caution.

Presence or absence in the PRA area (refer to section 2.1.1.2)

Determination of presence or absence in the PRA area is a particular challenge for NPPOs when plants are proposed for import because the plants may already be growing in locations (e.g. botanical gardens, home gardens) that may not be reported. Sources of information may include horticultural, agricultural, forestry and aquaculture publications and databases. The NPPO may need to carry out particular surveys to obtain information on presence and distribution.

The presence or absence of wild or cultivated relatives in the PRA area should also be determined in the case where there is scientific evidence that the plant may hybridize with such local relatives.

Intended use

The PRA should include consideration of the intended use (refer to ISPM 32:2009) of the plants as this may affect the probability of establishment, spread and economic consequences. However, it should also be recognized that plants, once entered, may escape or be diverted from the use for which they were originally intended.

In the case of plants for planting, significant human effort is made to ensure their continuous survival and, in some cases, successful reproduction because of their perceived benefits. Furthermore, the plants for planting have often been selected to be well suited for growing in the importing country. This significantly increases the likelihood of establishment and spread. Therefore, plants for planting are generally considered to pose the highest risk. Examples of uses, broadly in the order of decreasing risk at the time of planting, are:

- planting in the open landscape without management (e.g. for soil erosion control, waste water treatment and carbon dioxide uptake, or as aquatic plants in watercourses or ponds)
- planting in the open landscape with management (e.g. in forestry, agriculture (including for biofuel), horticulture, land reclamation and golf courses, or as cover crops)
- planting outdoors in urban areas (e.g. for amenity purposes in roadsides, parks or gardens)
- planting indoors only.

Plants for intended uses other than planting may be considered, including for human consumption or animal feed, processing, combustion for energy production, or research.

Habitats, locations and endangered areas

Plants imported for planting may be destined for a particular geographic location of a particular habitat. However, the NPPO should assess:

- the probability that the plants could establish in habitats in the PRA area other than where they were intended to grow (i.e. to what degree other habitats are suitable for the plant)
- the probability that the plants could spread from the location where they were intended to grow.

The overall area of suitable habitats where the presence of the plant would result in economically important loss constitutes the endangered area.

The analysis of suitable habitats is analogous to the analysis of host plants for other pests (in the case of parasitic plants, both host and habitat need to be considered). The guidance provided in section 2.2.2 (and its subsections) of this standard can generally be used, substituting the terms “host” and “host range” with “suitable habitat”.

Probability of entry (refer to section 2.2.1)

For imported plants, the probability of entry need not be assessed. Nevertheless, an estimation of the volume, frequency and destinations of prospective imports may be needed in order to assess the likelihood of establishment and spread.

Historical evidence of pest behaviour

The most reliable predictor of establishment, spread and potential economic consequences of a plant as a pest is the history of that plant as a pest when introduced into new areas with similar habitats and climate. Where such a history is documented, the assessment should use this information, comparing whether the habitat and climate conditions are sufficiently similar in the PRA area. However, a plant may never have been moved out of its native range where it may be controlled by naturally occurring enemies or other biotic or abiotic factors. In such cases, no historical evidence exists of establishment, spread or economic consequences.

Probability of establishment (refer to section 2.2.2)

The assessment of the probability of establishment should consider the suitability of the climate, other abiotic and biotic factors (see section 2.2.2.2), and cultural practices (see section 2.2.2.3). The

assessment should compare the conditions in habitats within the PRA area to the conditions in habitats in which the plant currently occurs. Depending on the information available, the following may be incorporated:

- *climate:* suitability of current climates and, for long-lived plants, future projected climates
- *other abiotic factors:* soil characteristics, topography, hydrology, natural fires, etc.
- *biotic factors:* current vegetation, degree of disturbance, presence or absence of natural enemies and competitors
- *cultural practices in crops or managed plant communities:* herbicide usage, harvesting, soil cultivation, burning, etc. (including side-effects such as aerial deposition of nitrogen or pesticides).

Where the history of a particular plant as a pest is not well documented, the assessment should consider intrinsic characteristics of the plant that may predict establishment (refer to section 2.2.2.4). Although intrinsic characteristics have sometimes been shown to be poor predictors, the following may be considered:

- *reproductive characteristics:* sexual and asexual mechanisms, dioecism, duration of flowering, self-compatibility, reproduction frequency, generation time
- *adaptive potential (of individuals and populations):* genotypic or phenotypic plasticity, hybridization potential
- *propagule attributes:* volume and viability, dormancy
- *tolerance or resistance:* response to pests, herbicides, grazing and other cultural practices, drought, flooding, frost, salinity, climate changes.

Many plants as pests are opportunists with a strong potential to become established in disturbed habitats. Plants with a robust dormancy combined with a prolific reproductive ability are particularly suited for such an opportunistic strategy. Disturbed habitats are common; therefore, plants with such opportunistic adaptations may encounter many opportunities for establishment and spread.

Probability of spread (refer to section 2.2.3)

The likelihood and extent of spread depends on natural and human-mediated factors. Natural factors may include:

- intrinsic characteristics of the plant species (in particular regarding reproduction, adaptation and propagule dispersal)
- existence of natural means of spread (e.g. birds and other animals, water, wind)
- existence and spatial pattern of suitable habitats and dispersal corridors connecting them.

Human-mediated factors, whether intentional or unintentional, may include:

- intended use, consumer demand, economic value and ease of transport
- the movement of propagules as a contaminant of soil or other materials (e.g. clothing, conveyances, machinery, tools, equipment)
- the discarding of plants (e.g. after flowering or when private aquaria are emptied)
- disposal procedures (e.g. composting) for waste that contains plants.

There are often long time lags between a plant's initial introduction and its later spread. As a consequence, even in the cases where establishment may be well documented, the potential for later spread may be less known. If evidence exists, the following factors may need to be considered:

- changes in abiotic factors (e.g. an increase in aerial deposition of nitrogen or sulphur)
- changes in the genetic profile of the plant species (e.g. through natural selection, genetic drift)
- long generative time or time to maturity
- emergence of novel uses for the plant
- relatively rare dispersal events that move propagules from suboptimal to optimal habitats

- changes in land use or disturbance pattern (e.g. following natural floods, natural fires)
- changes in climate (e.g. warmer climate changes in precipitation patterns).

Assessment of potential economic consequences (refer to section 2.3)

Plants as pests may have a variety of economic consequences, including yield losses in agriculture, horticulture and forestry; reduction of recreational value; or reduction of biodiversity and negative effects on other parts of the ecosystem. Assessment of economic consequences of plants as pests may be inherently difficult because they may have broad agricultural, environmental and social consequences that may be non-specific, not readily apparent or not easily quantified (e.g. changes in the soil's nutrient profile).

It is important to consider the potential long-term economic consequences for the entire PRA area, including where the plants are intended to grow. The most reliable predictor of potential economic consequences is evidence of consequences elsewhere, particularly in areas with similar habitats. However, in some cases, plants have never been moved out of their native ranges and therefore may not have had an opportunity to express any potential consequences. In the absence of evidence of economic consequences elsewhere, consideration may be given to whether or not the plant possesses intrinsic characteristics that predict pest potential, such as those discussed above and in section 2.2.2.4 related to establishment and spread.

Stage 3: Pest risk management (refer to section 3.4)

Plants for planting will usually be introduced into habitats suitable for their establishment and growth. In such cases, most pest risk management options would be counterproductive to the intended use. In general, for plants for planting considered quarantine pests, the most effective risk management option is prohibition (refer to section 3.4.6). However, those plants may at the same time have a perceived benefit that may be considered in the decision-making process following the PRA.

For specific situations, other pest risk management options may be pursued, including:

- requirements for growing plants under confinement
- requirements for harvesting plants at a certain stage or specified time to prevent opportunities for reproduction
- restriction of plants to particular locations, such as those that are marginally suitable
- restriction of import to specified cultivars or clones
- restrictions on the disposal of excess or waste plant material
- other restrictions on planting, growing, sale, holding, transport or disposal
- considering the use of codes of conduct for sale, holding, transport, planting or disposal, for example, in the form of internal rules or guidelines within the plant industry to refrain from or restrict the selling of particular plants for specific intended uses.

For plants imported for consumption or processing, risk management options may include restrictions on transport, storage, locations of import and use, sale, waste disposal, time of year import takes place, and requirements regarding the processing or treatments (e.g. devitalization).

In identifying risk management options, the suitability of control measures, ease of detection, identification of and access to the plants, time needed for effective control and difficulty of eradication or containment should be considered. For example, plants in highly managed systems such as cropping systems may be more easily controlled than plants in natural or semi-natural habitats, or in private gardens. Many of the factors considered under "establishment" and "spread" also influence a plant's response to control measures and thus the feasibility of control.

In cases where the assessed plants are present in collections (e.g. botanical gardens) and import regulation is considered, phytosanitary measures may have to be applied to those collections.

Irrespective of risk management options, where the import of a plant is allowed, it may be appropriate to develop post-entry systems such as surveillance in the PRA area, contingency plans, and systems to report new occurrences.

Aspects common to all PRA stages

Risk communication (refer to ISPM 2:2007)

Plants intentionally introduced for planting may not be perceived as a threat by the public, or by particular stakeholders, who may perceive the plants as purely beneficial. Furthermore, in many countries authorities other than the NPPO have responsibilities under the Convention of Biological Diversity with regard to plants intentionally introduced for planting. Therefore, risk communication may be particularly important in relation to plants as pests.

Risk communication may include for example:

- consultation with importers, research institutes and other governmental and non-governmental organizations (e.g. environmental protection agencies, parks departments, nurseries, landscapers) to exchange information on plants as potential pests
- publication of lists of plants as quarantine pests
- labelling of plants in commerce (e.g. explaining the pest risk the plants may pose and under which conditions the pest risk may occur).